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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,415	02/17/2004	Chong-Qing Sun	LA0087A CIP	1307

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/780,415

Applicant(s)

SUN ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04/05/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 05/01/06, 10/12/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

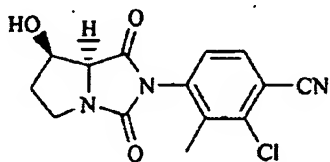
1. This application claims benefit of the provisional application:  
60/381,616 with a filing date 05/17/2002; and  
60/406,711 with a filing date 08/29/2002.
2. Claims 1-21 are pending in the application.

### Information Disclosure Statement

3. Applicant's Information Disclosure Statements, filed on May 01, 2006, October 12, 2004, or March 19, 2004, have been considered. Please refer to Applicant's copy of the 1449 submitted herein.

### Responses to Election/Restriction

4. Applicant's election with traverse of Group I claims 1-7 and 12, in part, in the reply filed on April 05, 2006, is acknowledged. An elected species, i.e.,



, is also acknowledged. The traversal is on the grounds that applicants do not believe that a serious burden would be imposed upon the Examiner to search the Applicants' claimed genus of compounds. This is not found persuasive and reasons are given, *infra*.

Claims 1-21 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-7 and 12, in part, drawn to compounds/compositions of formula (I),

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wherein the variables  $R_1$ ,  $R_2$ ,  $R_2'$ ,  $R_4$ ,  $R_4'$ ,  $R_5$ ,  $R_5'$ ,  $R_6$ ,  $R_6'$ , or  $W$  independently does not represent heteroaryl or heterocycle, the variables  $R_1$ ,  $R_2$ ,  $R_2'$ ,  $R_4$ ,  $R_4'$ ,  $R_5$ ,  $R_5'$ ,  $R_6$ ,  $R_6'$ , or  $W$  independently is not substituted with heteroaryl or heterocycle; the variable  $G$  does not represent heteroaryl or heterocycle, and the variable  $G$  is not substituted with heteroaryl or heterocycle thereof; the variable  $n$  is an integer of 1 thereof.

The withdrawn compounds/compositions, processes of making, or methods of use contain varying heterocycle or heteroaryl of the variable  $G$ ,  $R_1$ ,  $R_2$ ,  $R_2'$ ,  $R_4$ ,  $R_4'$  or  $R_5$  of the formula (I) having morpholine, pyridyl, or piperazine moiety, which differ from those of the elected invention having imidazole or pyrrolidine moiety, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e., class 544 subclass 106(+) (morpholine), class 546 subclass 249(+) (pyridyl), class 544 subclass (336+) (piperazine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in common structure and composition and have been restricted properly.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on

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the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-7 and 12, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-7 and 12, in part, not embraced in above elected subject matter, and claims 8-11 and 13-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

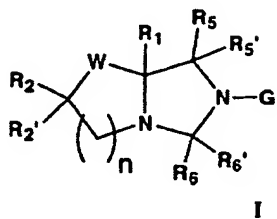
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Kelly et al. US 6,365,615.

Applicants claim an imidazole compound/composition of formula (I), i.e.,

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I, see claims 1 and 12. Dependent claims 2-7 of claim 1

further limit the variable G, R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, or R<sub>4</sub>' of formula (I), i.e., the variable R<sub>1</sub> represents hydrogen or alkyl.

Kelly et al. disclose six imidazole compounds, i.e., 2-(3,5-Dichlorophenyl)-7-(R\*)-phenyl-7a-(R\*)-tetrahydropyrrolo[1,2-c]imidazole-1,3-dione; 2-(3,5-Dichlorophenyl)-7a-(R\*)-methyl-7-(R\*)-phenyl-tetrahydropyrrolo[1,2-c]imidazole-1,3-dione; 7-(R\*)-(4-Bromophenyl)-2-(3,5-dichlorophenyl)-7a-(R\*)-tetrahydropyrrolo[1,2-c]imidazole-1,3-dione; 7-(R\*)-(4-Bromophenyl)-2-(3,5-dichlorophenyl)-7a-(R\*)-methyl-tetrahydropyrrolo[1,2-c]imidazole-1,3-dione; 7-(R\*)-(4-Bromophenyl)-2-(3,5-dichlorophenyl)-6-(S\*)-hydroxy-7a-(R\*)-tetrahydropyrrolo[1,2-c]imidazole-1,3-dione, and 7-(R\*)-(4-Bromophenyl)-2-(3,5-dichlorophenyl)-7a-(R\*)-allyl-tetrahydropyrrolo[1,2-c]imidazole-1,3-dione, or their pharmaceutically acceptable salt thereof, see columns 40, 28, and 33-34 respectively. Kelly et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable n is 1; the variable G represents aryl (i.e., phenyl) substituted with halo (i.e., Cl); the variable R<sub>5</sub> and R<sub>5</sub>' taken together form a double bond with oxygen; the variable R<sub>6</sub> and R<sub>6</sub>' taken together form a double bond with oxygen; the variable R<sub>1</sub> represent hydrogen or alkyl (i.e., methyl) or substituted alkyl (i.e., CH<sub>2</sub>CH=CH<sub>2</sub>); the variable W represents C(R<sub>6</sub>)(R<sub>6</sub>'), and R<sub>6</sub> or R<sub>6</sub>' independently represents hydrogen or substituted aryl (i.e., phenyl substituted with Br); the variable R<sub>2</sub>

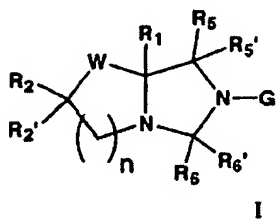
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or  $R_2$  independently represents hydrogen or  $OR_3$  and  $R_3$  is hydrogen. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under 35 U.S.C. 102(a) and (e).

7. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Sun et al. US 6,670,386.

The applied reference has a common inventor or assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants claim an imidazole compound/composition of formula (I), i.e.,



, see claims 1 and 12. Dependent claims 2-7 of claim 1 further limit the variable G,  $R_1$ ,  $R_2$ ,  $R_2'$ ,  $R_4$ , or  $R_4'$  of formula (I), i.e., the variable  $R_1$  represents hydrogen or alkyl.

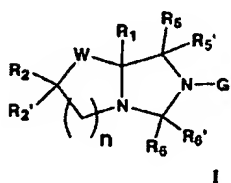
Sun et al. disclose a number of imidazole compounds, see examples No. 6, 12-15, 23-29, 30-33 and 41 in columns 37, 42, 45-46, 55, 57, 63, or see 2nd, 6th, 8th-13th

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compounds of claim 4 in columns 65-67 respectively. Sun et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable  $n$  is 1; the variable  $G$  represents aryl (i.e., naphthalene) substituted with CN, halo (i.e., Br), or  $\text{CO}_2\text{R}_4$ , and  $\text{R}_4$  is alkyl (i.e., methyl); the variable  $\text{R}_5$  and  $\text{R}_5'$  taken together form a double bond with oxygen; the variable  $\text{R}_6$  and  $\text{R}_6'$  independently represents hydrogen alkyl (i.e., butyl) or aryl (i.e., phenyl) or the variable  $\text{R}_6$  and  $\text{R}_6'$  taken together form a double bond with oxygen; the variable  $\text{R}_1$  represent hydrogen or alkyl (i.e., methyl); the variable  $W$  represents  $\text{C}(\text{R}_6)(\text{R}_6')$ , and  $\text{R}_6$  or  $\text{R}_6'$  independently represents hydrogen or alkyl (i.e., methyl) or the variable  $W$  represents  $\text{C}(\text{R}_6)\text{OR}_3$ , and  $\text{R}_6$  represents hydrogen and  $\text{R}_3$  represents hydrogen or  $\text{R}_3$  represents  $\text{COR}_4$  and  $\text{R}_4$  represents alkyl (i.e., methyl); the variable  $\text{R}_2$  or  $\text{R}_2'$  independently represents hydrogen or  $\text{OR}_3$  and  $\text{R}_3$  is hydrogen. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under 35 U.S.C. 102(e).

8. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Palovich et al. WO 00/72845.

Applicants claim an imidazole compound/composition of formula (I), i.e.,



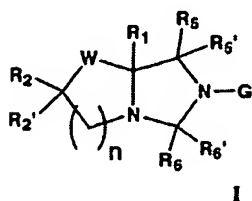
, see claims 1 and 12. Dependent claims 2-7 of claim 1 further limit the variable  $G$ ,  $\text{R}_1$ ,  $\text{R}_2$ ,  $\text{R}_2'$ ,  $\text{R}_4$ , or  $\text{R}_4'$  of formula (I), i.e., the variable  $\text{R}_1$  represents hydrogen or alkyl.



Palovich et al. disclose two imidazole compounds, i.e., 4-[[[(7aS)-2-(2-bromophenyl)-hexahydro-1-oxo-3H-pyrrolo[1,2-c]imidazol-3-ylidene]amino]-3-hydroxybenzonitrile; and 4-[[[(6R,7aS)-2-(2-bromophenyl)-hexahydro-6-hydroxy-1-oxo-3H-pyrrolo[1,2-c]imidazol-3-ylidene]amino]-3-hydroxybenzonitrile, see page 7, lines 11-12 and 15-16, also see RN: 311319-99-0 or 311320-01-1 of CAS:134:25357. Palovich et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable n is 1; the variable G represents any (i.e., phenyl) substituted with halo (i.e., Br); the variable R<sub>5</sub> and R<sub>5'</sub> taken together form a double bond with oxygen; the variable R<sub>6</sub> and R<sub>6'</sub> taken together form a double bond with NR<sub>7</sub> and R<sub>7</sub> represent substituted any (i.e., phenyl substituted with CN, or OH); the variable R<sub>1</sub> represent hydrogen; the variable W represents C R<sub>6</sub> R<sub>6'</sub>, and R<sub>6</sub> or R<sub>6'</sub> independently represents hydrogen; the variable R<sub>2</sub> or R<sub>2'</sub> independently represents hydrogen. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under 35 U.S.C. 102(b).

9. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Issartel et al. publication, European Journal of Medicinal Chemistry (1996), 31(9), 717-723, see CAS: 125:316198.

Applicants claim an imidazole compound/composition of formula (I), i.e.,

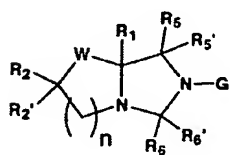


, see claims 1 and 12. Dependent claims 2-7 of claim 1 further

Issartel et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable n is 1; the variable G represents aryl (i.e., phenyl) or aryl (i.e., phenyl) substituted with halo (i.e., Cl); the variable R<sub>5</sub> and R<sub>5'</sub> taken together form a double bond with oxygen; the variable R<sub>6</sub> and R<sub>6'</sub> taken together form a double bond with oxygen; the variable R<sub>1</sub> represent hydrogen; the variable W represents C R<sub>6</sub> R<sub>6'</sub>, and R<sub>6</sub> or R<sub>6'</sub> independently represents hydrogen; the variable R<sub>2</sub> or R<sub>2'</sub> independently represents hydrogen or OR<sub>3</sub> and R<sub>3</sub> is hydrogen. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under 35 U.S.C. 102(b).

10. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sircar et al. WO 01/30781, also see US 6,896,225.

Applicants claim an imidazole compound/composition of formula (I), i.e.,



<sup>1</sup>, see claims 1 and 12. Dependent claims 2-7 of claim 1 further

limit the variable G, R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, or R<sub>4</sub>' of formula (I), i.e., the variable R<sub>1</sub> represents hydrogen or alkyl.

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Sircar et al. disclose a number of imidazole compounds, i.e., compound No. 43 of Table 2 on column 43, Examples 110-127, 129-129, 138-140, 142, 155-158, 170-182, 189-190, 193, 209-216, 220, 222-224, 230, 232-235, 238, 240, 266-268, and 310-311 on columns 67-119. Sircar et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable n is 1; the variable G represents aryl (i.e., phenyl), or substituted aryl, i.e., phenyl substituted with halo (i.e., Br or Cl), CN, CF<sub>3</sub>, OR<sub>4</sub>, and R<sub>4</sub> is hydrogen or methyl, or NR<sub>4</sub>R<sub>4</sub>', and R<sub>4</sub> or R<sub>4</sub>' independently represents hydrogen; the variable R<sub>5</sub> and R<sub>5</sub>' taken together form a double bond with oxygen; the variable R<sub>6</sub> and R<sub>6</sub>' taken together form a double bond with oxygen; the variable R<sub>1</sub> represent arylalkyl (i.e., phenylmethyl or phenylphenylmethyl) or substituted arylalkyl, i.e., phenylmethyl substituted with Br, CN, -SOCF<sub>3</sub>, -SOMe, SO<sub>2</sub>Me, -CO<sub>2</sub>Me, -CHCHCO<sub>2</sub>Me, CN, NH<sub>2</sub>, or phenylphenylmethyl substituted with CH<sub>3</sub>SO<sub>2</sub>NH-, NH<sub>2</sub>, or NO<sub>2</sub>; the variable W represents C R<sub>6</sub> R<sub>6</sub>', and R<sub>6</sub> or R<sub>6</sub>' independently represents hydrogen; the variable R<sub>2</sub> or R<sub>2</sub>' independently represents hydrogen or OR<sub>3</sub>, and R<sub>3</sub> is hydrogen. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under 35 U.S.C. 102(b).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

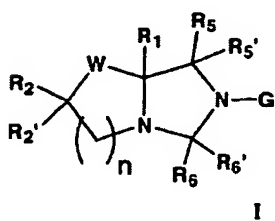
“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re

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Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

12. Claims 1-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sircar et al. WO 01/30781, also see US 6,897,225.

Applicants claim a compound/composition of formula (I), i.e.,

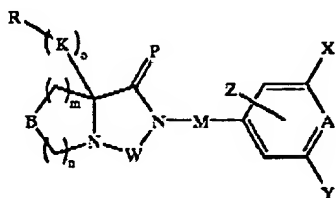


, see claims 1 and 12. Dependent claims 2-7 of claim 1

further limit the variable G, R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, or R<sub>4</sub>' of formula (I), i.e., the variable R<sub>1</sub> represents hydrogen or alkyl.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

Sircar et al. disclose a compound/composition of formula (I), i.e.,



, wherein the variable A represents C(Z<sup>1</sup>) (i.e., CH); the

variable P represents O or S; the variable W represents C=O; the variable B represents -C(R<sup>1</sup>)(R<sup>2</sup>)-, and R<sup>1</sup> or R<sup>2</sup> independent represents hydrogen, halogen; the variable m or n independently represents 1; the variable M represents a single bond, the variable R represents optionally substituted aryl, the variable o represents 1 or 2, and the variable

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K represents  $-\text{CH}_2-$ , the variable Z or Y independent represents hydrogen, halogen, OH, NO<sub>2</sub>, or CN, see columns 122-131.

**Determination of the difference between the prior art and the claims (MPEP**

**§2141.02)**

The difference between instant claims and Sircar et al. is that the instant variable G independently represents aryl, while Sircar et al. represents aryl or pyridyl at the same position.

**Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)**

One having ordinary skill in the art would find the claims 1-7, and 12 prima facie obvious because one would be motivated to employ the compounds/compositions and methods of use of Sircar et al. to obtain instant claimed compounds/compositions, wherein the variables R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, R<sub>4</sub>' R<sub>5</sub>, R<sub>5</sub>' R<sub>6</sub>, R<sub>6</sub>', or W independently does not represent heteroaryl or heterocycle, the variables R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, R<sub>4</sub>' R<sub>5</sub>, R<sub>5</sub>' R<sub>6</sub>, R<sub>6</sub>', or W independently is not substituted with heteroaryl or heterocycle; the variable G does not represent heteroaryl or heterocycle, and the variable G is not substituted with heteroaryl or heterocycle thereof; the variable n is an integer of 1 thereof, and the variable R<sub>1</sub> represents arylalkyl or substituted arylalkyl. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under obviousness-type double patenting as the same reasons above.

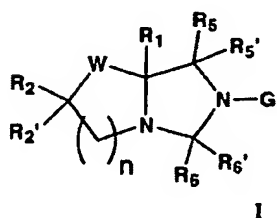
The motivation to make the claimed products derives from the expectation

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that the instant claimed compounds/compositions derived from known Sun et al. compounds/compositions would possess similar activities (i.e., agents of pharmaceuticals) to that which is claimed in the reference.

13. Claims 1-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. US 6,365,615.

Applicants claim a compound/composition of formula (I), i.e.,

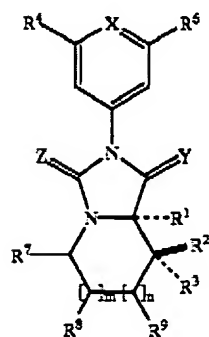


, see claims 1 and 12. Dependent claims 2-7 of claim 1

further limit the variable G, R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, or R<sub>4</sub>' of formula (I), i.e., the variable R<sub>1</sub> represents hydrogen or alkyl.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

Kelly et al. disclose a compound/composition of formula (I), i.e.,



, wherein the variable X represents =CH-; the variable Y or Z

represents O; the variable m represents 0, the variable n represents 1; the variable R<sup>2</sup>

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represents optionally substituted phenyl; the variable  $R^1, R^3, R^4, R^6, R^7$ , or  $R^8$  independent represents hydrogen, methyl, or Cl, see columns 38-40.

**Determination of the difference between the prior art and the claims (MPEP**

**§2141.02)**

The difference between instant claims and Kelly et al. is that the instant variable G independently represents aryl, while Kelly et al. represents aryl or pyridyl at the same position.

**Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)**

One having ordinary skill in the art would find the claims 1-7, and 12 prima facie obvious because one would be motivated to employ the compounds/compositions and methods of use of Sircar et al. to obtain instant claimed compounds/compositions, wherein the variables  $R_1, R_2, R_2', R_4, R_4', R_5, R_5', R_6, R_6'$ , or W independently does not represent heteroaryl or heterocycle, the variables  $R_1, R_2, R_2', R_4, R_4', R_5, R_5', R_6, R_6'$ , or W independently is not substituted with heteroaryl or heterocycle; the variable G does not represent heteroaryl or heterocycle, and the variable G is not substituted with heteroaryl or heterocycle thereof; the variable n is an integer of 1 thereof, and the variable W represents  $CR_6R_6'$ , i.e., aryl or substituted aryl. Dependent claims 2-7 and 12 of claim 1 are also rejected along with claim 1 under obviousness-type double patenting as the same reasons above.

The motivation to make the claimed products derives from the expectation



that the instant claimed compounds/compositions derived from known Kelly et al. compounds/compositions would possess similar activities (i.e., agents of pharmaceuticals) to that which is claimed in the reference.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

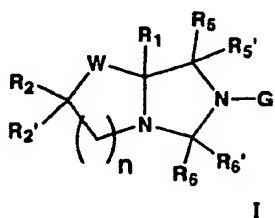
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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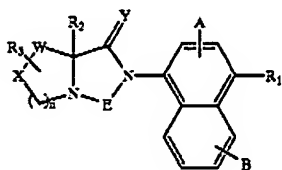
15. Claims 1-7 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of Sun et al. US 6,670,386. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a compound/composition of formula (I), i.e.,



, see claims 1 and 12, as agents treating aged-related diseases associated with the androgen receptors. Dependent claims 2-7 of claim 1 further limit the variable G, R<sub>1</sub>, R<sub>2</sub>, R<sub>2</sub>', R<sub>4</sub>, or R<sub>4</sub>' of formula (I), i.e., the variable R<sub>1</sub> represents hydrogen or alkyl.

Sun et al. claim a compound/composition of formula (I), i.e.,



, wherein the variable E represents C=O or C=S; the variable Y represents O or S; the variable W represents CR<sub>6</sub>R<sub>6</sub>'; the variable X represent -CH<sub>2</sub>-; the variable R<sub>3</sub> represent OR<sub>4</sub>(i.e., OH); the variable A, B, or R<sub>2</sub> independently represents hydrogen, halo, cyano, or nitro, see columns 64-68.

The difference between instant claims and Sun et al. is that the instant variable G independently represents aryl, while Sun et al. represents naphthalene at the same position.

One having ordinary skill in the art would find the claims 1-7, and 12 prima facie obvious because one would be motivated to employ the compounds/compositions and methods of use of Sun et al. to obtain instant claimed compounds/compositions, wherein the variables  $R_1$ ,  $R_2$ ,  $R_2'$ ,  $R_4$ ,  $R_4'$ ,  $R_5$ ,  $R_5'$ ,  $R_6$ ,  $R_6'$ , or W independently does not represent heteroaryl or heterocycle, the variables  $R_1$ ,  $R_2$ ,  $R_2'$ ,  $R_4$ ,  $R_4'$ ,  $R_5$ ,  $R_5'$ ,  $R_6$ ,  $R_6'$ , or W independently is not substituted with heteroaryl or heterocycle; the variable G does not represent heteroaryl or heterocycle, and the variable G is not substituted with heteroaryl or heterocycle thereof; the variable n is an integer of 1 thereof. Dependent claims 2-7 of claim 1 are also rejected along with claim 1 under obviousness-type double patenting as the same reasons above.

The motivation to make the claimed products derives from the expectation that the instant claimed compounds/compositions derived from known Sun et al. compounds/compositions would possess similar activities (i.e., agents treating aged-related diseases associated with the androgen receptors) to that which is claimed in the reference.

### ***Claim Objections***

16. Claims 1-7 and 12 are objected to as containing non-elected subject matter, i.e., heterocyclo or heteroaryl, pyridyl, the variable n represents 2, the variable J, K, L, P and Q represents O, S, SO, the second or third compound of claim 5, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

17. Claim 1 recite the term "including all prodrug esters" is objected, see page 229,

line 23. Replacement of the term "including all prodrug esters" with the term "all prodrug esters of formula I" would obviate the objection.


18. Claim 2, line 2, is objected. Incorporation of a term "and" after the third formula would obviate the objection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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May 18, 2006

  
Joseph K. McKane  
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